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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/055,744	04/07/1998	CHARLES D. Y. SIA	1038-746-MIS	4350

7590 01/13/2005

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/055,744	SIA ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 November 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1 and 4-15 are currently pending and under examination.

Drawings

2. The drawings are objected to because the newly submitted drawings are not as originally filed. Applicants' attention is directed to Figure 1, there is no data charting for CLP-178 in the newly submitted drawings, whereas, the original drawings contain data charting for CLP-178.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 4-11 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons set forth in the previous office action.

Applicants submit that claims as presented are not directed to a treatment method for HIV infection. Applicants submit that the invention is directed to a method of generating HIV-specific cytotoxic T-cell responses in a host, which is illustrated by using peptides that correspond to a portion of the hepatitis B virus nucleocapsid antigen and certain lipopeptides derived from the REV protein of HIV-1. Applicants further submit

that they have provided sound immunization protocols for inducing HIV-specific cytotoxic T-cell responses in a host by the administration of peptides that correspond to a portion of the hepatitis B virus nucleocapsid antigen to prime the immune system of the host, followed by administration of a mixture of the peptides that correspond to a portion of the hepatitis B virus nucleocapsid antigen and certain lipopeptides derived from the REV protein of HIV-1. Applicants additionally submit that the present invention is based on the findings that certain peptides are also capable of eliciting CTL as well as antibody responses in HLA-A2 transgenic mice.

Applicants' above submission has been considered, however, it is not found persuasive. The issue at hand is that the claimed method, in view of the specification, reads on a method of treating or preventing HIV infection. While this is not explicitly recited in the claims, however, claimed subject matter is interpreted in view of the disclosure. In the instant, the claims recite a method of generating an HIV-specific cytotoxic T-cell response in a host. However, what biological activity can be ascertained by the generation of an HIV-specific cytotoxic T-cell response in a host? Is it to increase viral load, decrease viral load or to detect the virus? The biological activity that can be ascertained by the implementation of the claimed method is not readily apparent in the claims. Thus, the Examiner turns to the specification to ascertain this information, which discloses the following:

- lines 26-31 of page 1, disclose that Applicants' interest in HIV vaccinology is to develop synthetic HIV-1 peptide vaccines for the elicitation of more effective immune response against HIV-1.

- lines 9-24 of page 2, discuses that Applicants' present effort is the design of HIV vaccines capable of eliciting cell-mediated immunity and protocols for the use thereof. In view of this effort, the inventors focused on a viral peptides containing REV protein, which "may be presented in the context of the Major Histocompatibility Complex (MHC) class 1 molecules to induce CTL effector response capable of killing virus infected cells early to limit virus spread." The instantly claimed invention comprises the administration of peptides that are derived from the Rev protein. These peptides are presented in the context of the Major Histocompatibility Complex (MHC) class I molecules because the claims require that the T-cell inducing HIV molecule is capable of binding to MHC class I molecules.
- lines 22-25 of page 4, discloses that the advantages of the present invention include an immunization procedure to induce a T-cell response in a host and immunogenic peptides for use in such procedures.
- bridging paragraph on pages 5-6, discloses that based on the experimentation provided, Applicants provide a novel immunization protocol for inducing HIV-specific cytotoxic T-cell response.
- lines 25-29 of page 9 of the specification discloses that the components employed in the claimed invention are administered in a manner compatible with the dosage formulation, and in such amount as will be therapeutically effective, immunogenic and protective in the immunization protocol.

Ergo, in view of the disclosure provided by Applicants, the Examiner concludes that the intended purpose of the claimed invention is directed at a protocol for the treatment for and/or prevention of HIV. Therefore, in view of what is currently presented in the claims, in light of the disclosure provided in the specification, it is concluded that the full breadth of the claimed invention encompasses an *in vivo* vaccine method that is used to treat, prevent, or inhibit the progression of HIV infection in humans and non-human animals by generating an HIV-specific CTL response in the host. Furthermore, the Examiner's position is further affirmed the admission that Applicants have devised a sound "**immunization** [emphasis added] protocol". Immunization is protection of susceptible individuals from communicable diseases; and the production of immunity, according to Stedman's Medical Dictionary, 27th Edition.

In view of Applicants' submission and the discussion above, the claims remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Double Patenting

5. Claims 1 and 4-11 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4-11 of copending Application No. 09/647,981 for reason(s) set forth in the previous office action.

Conclusion

6. Claim 12-15 is allowable as currently presented.

7. **THIS ACTION IS MADE FINAL.** Applicants is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey S. Parkin, Ph.D.
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